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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/978,386   | 10/16/2001  | James F. Zucherman   | KLYC-01055US1       | 4255             |
| 23910  | 7590        | 07/06/2004           | EXAMINER            |                  |
| FLIESLER MEYER, LLP<br>FOUR EMBARCADERO CENTER<br>SUITE 400<br>SAN FRANCISCO, CA 94111 |             |                      | BUI, VY Q           |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 3731                 |                     |                  |
| DATE MAILED: 07/06/2004  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                  |
|------------------------------|-----------------|------------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)     |
|                              | 09/978,386      | ZUCHERMAN ET AL. |
|                              | Examiner        | Art Unit         |
|                              | Vy Q. Bui       | 3731             |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 April 2004.  
 2a) This action is **FINAL**.                                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 42-46 and 54-63 is/are pending in the application.  
 4a) Of the above claim(s) 42-46 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 54-63 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

4)  Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5)  Notice of Informal Patent Application (PTO-152)  
 6)  Other: \_\_\_\_\_.

**DETAILED ACTION*****Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 54-55, 58-59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over ZUCHERMAN et al. (5,836,948).

As to claims 54-55, 58-59, ZUCHERMAN-'948 (Fig. 40; col. 9, lines 36-60) discloses hollow dilator/cannula 258 with handle portion/proximal portion 268, elongated body/mid portion of dilator/cannula 258, conical tapered curved tip 266 and a series of dilators 258, with each subsequent dilator/cannula being slightly bigger than a preceding dilator so that the subsequent larger dilator can be placed over the preceding smaller dilator and the smaller dilator can be withdrawn from the center of the subsequent larger dilator. Although Fig. 40 only shows one hollow dilator/cannula 258 and does not show another subsequent larger dilator, however, subsequent larger dilator must have a curved tip so that the subsequent larger dilator can be placed over the preceding smaller dilator (col. 9, lines 51-60), because if the tip of the subsequent larger dilator is straight, one can not place the subsequent larger dilator over the curved tip of the preceding smaller dilator in a process as disclosed by ZUCHERMAN. Alternatively, in view of ZUCHERMAN-'948, it would be obvious to one of ordinary skill in the art to provide a

series of dilators having the 2<sup>nd</sup> diameter of a preceding dilator being the same as the 1<sup>st</sup> diameter of a subsequent dilator so as one can make an opening gradually enlarged.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 56-57 and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZUCHERMAN et al. (5,836,948).

As to claims 56-57 and 60-63, ZUCHERMAN-'948 discloses inherently a series of dilators as claimed. ZUCHERMAN-'948 does not disclose color codes or measuring marks for indication of a range of diameters of a dilator or a width of a dilated opening. However, color-coding/marketing a medical device to indicate a range of variables/values applicable for the device is well known. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a color code for a ZUCHERMAN-'948 device so that a user of a dilator can quickly recognize and get the suitable dilator applicable for a specific range of application during a medical operation.

***Response to Amendment***

The amendment filed on 4/12/2004 under 37 CFR 1.131 has been considered but is ineffective to overcome ZUCHERMAN-'948 reference as presented in the above rejection.

***Conclusion***

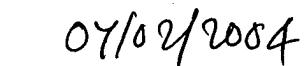
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Vy Q. Bui  
Primary Examiner